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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/774,144	02/06/2004	Durlin Hickok	17101-025001 / 24727-826	8562

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EXAMINER	
GRUN, JAMES LESLIE	
ART UNIT	**PAPER NUMBER**
1641	

DATE MAILED: 09/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/774,144	HICKOK ET AL.	
	Examiner	Art Unit	
	James L. Grun	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 August 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15 and 17-64* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-15 and 17-64* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

The amendment filed 18 August 2006 is acknowledged and has been entered. Claim 16 has been cancelled. Claims 1-15 and 17-64 remain in the case.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Notwithstanding applicant's characterization to the contrary in the response filed 18 August 2006, the examiner did not make comment or suggestion in the prior Office action on applicant's compliance with applicant's duty to disclose information material to patentability. The examiner notes that, based on applicant's response, applicant has either declined invitation, or sees no need, to aid examination by pointing to any other documents of particular relevance not cited by the examiner.

The specification is objected to and claims 1-5, 7-12, 15, 17-24, 26-44, 47, and 49-64 are rejected under 35 U.S.C. § 112, first paragraph, for the reasons of record that the specification contains subject matter which was not described in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, particularly the invention commensurate in scope with these claims.

Applicant's arguments filed 18 August 2006 have been fully considered but they are not deemed to be persuasive.

Applicant urges that the general principles of using progestational agents were well studied and developed. This is not found persuasive for the reasons of record that the art teaches large differences among the many agents considered to be progestational on the basis of

pharmacological tests and that the results of the use of progesterone-related agents generally for prolonging a pregnancy at risk for preterm delivery, the only reason for its use in the instant specification (see e.g. pages 1-3 or 6), were unknown and were unpredictable because only specific agents were tested and suggested to have that ability (see e.g. Goldstein et al. or Keirse or da Fonseca et al. or Meis et al.). Notwithstanding applicant's assertions to the contrary, applicant has provided nothing on the record to predictably link the use of a progesterone-related agent as a contraceptive (i.e., **preventing** a pregnancy, as in Spicer et al. or Peters et al.) to its successful use as an agent for **prolonging** a pregnancy at risk for preterm delivery. The specification merely suggests the use of agents that retain the activity of progesterone to inhibit or delay delivery, but provides no guidance for which agents retain such activity. It is also noted that applicant's specification provides no working examples of pregnancy prolongation other than that demonstrated in the art with progesterone (da Fonseca et al.) or 17α-hydroxyprogesterone (Johnson et al., Yemini et al., Keirse, or Meis et al.) or omega-3 fatty acid supplementation (Allen et al. or Olsen et al.). As set forth, random experimentation unguided by applicant to determine agents that do or do not function in the invention suggested by applicant's specification is undue experimentation.

Claims 35-64 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

With regard to claims 35-64, the specification, as originally filed, does not provide support for the sequential method as is now claimed. Applicant teaches monitoring the level of two markers (see e.g. page 5 or claim 26). Although one of skill in the art might realize from reading the disclosure that sequential determinations are useable in the invention, such possibility of use does not provide explicit or implicit indication to one of skill in the art that such were originally contemplated as part of applicant's invention and such possibility of use does not satisfy the written description requirements of 35 U.S.C. § 112, first paragraph. Note that a description which renders obvious a claimed invention is not sufficient to satisfy the written description requirement. Applicant is requested to direct the Examiner's attention to specific passages where support for these newly recited limitations can be found in the specification as filed or is required to delete the new matter.

Claims 1-7, 10, 11, 15, 21, and 39 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 1-7, the metes and bounds of the invention intended as encompassed by applicant are not clear because no components, only an intended use, are recited for the test system. One would not be apprised of the combination intended because applicant claims what the test system does, not what it is. In claim 2, only an antibody is recited in the test system and it remains unclear what other components are comprised and their interrelationships.

Claim 4 provides no further limitation of the combination as it only limits the intended use and does not appear to affect the components of the combination.

In claim 10, 11, and 15 the interrelationships of the further antibodies to the anti-(preterm delivery marker) antibody comprised by the solid support are not clear.

In claim 21, "the" ratio lacks antecedent basis.

In claim 39, "the" start lacks antecedent basis.

Applicant's arguments filed 18 August 2006 have been fully considered but they are not deemed to be persuasive. Notwithstanding applicant's assertions to the contrary, applicant's amendments have not obviated rejections under this statute for the reasons set forth above.

Notwithstanding applicant's assertions to the contrary, limitations from the specification are not imported into the claims unnecessarily. There remains no antecedent support for the "the ratio" in claim 21. It is noted that the level of the marker is monitored in the independent claim and that the marker as claimed is merely "the ratio" of unknown properties of estriol to progesterone because there is no indication that estriol or progesterone levels are monitored for calculation of a ratio. There remains no antecedent support for "the start" of organogenesis in claim 39. It is not clear that the term particularly points out a single time point as asserted by applicant. See also *In re Zletz*, 893 F.2d 319, 321-22, 13 USPQ2d 1320, 1322 (Fed. Cir. 1989) ("During patent examination the pending claims must be interpreted as broadly as their terms reasonably allow.... The reason is simply that during patent prosecution when claims can be amended, ambiguities should be recognized, scope and breadth of language explored, and clarification imposed.... An essential purpose of patent examination is to fashion claims that are precise, clear, correct, and unambiguous. Only in this way can uncertainties of claim scope be removed, as much as possible, during the administrative process.").

Claims 1-13, 17-19, 22-26, 30-31, 33, and 34 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Leavitt et al. (WO 94/17405) in view of any of Johnson et al. (NEJM 293: 675, 1975), Meis et al. (Am. J. Obstet. Gynecol. 187: S54, 2002), or Keirse (Br. J. Obstet. Gynaecol. 97: 149, 1990), and further in view of Weiner et al. or Andersen et al. for reasons of record in the prior rejection of the similar subject matter of these claims.

Claims 1-13, 15, 17-44, and 47-64 are rejected under 35 U.S.C. 103(a) as being unpatentable over Leavitt et al., in view of any of Johnson et al., Meis et al., or Keirse, and further in view of Weiner et al. or Andersen et al., and further in view of Dullien (US 5,480,776) for reasons of record in the prior rejection of the similar subject matter of these claims.

Claims 7, 14, 17-19, and 22-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Leavitt et al., in view of any of Johnson et al., Meis et al., or Keirse, and further in view of Weiner et al. or Andersen et al., and further in view of Allen et al. (Exp. Biol. Med. 226: 498, 2001) or Olsen et al. (Lancet 339: 1003, 1992) for reasons of record in the prior rejection of the similar subject matter of these claims.

Claims 7, 14, 17-25, 30-34, 45, and 46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Leavitt et al., in view of any of Johnson et al., Meis et al., or Keirse, further in view of Weiner et al. or Andersen et al., further in view of Dullien, and further in view of Allen et al. (Exp. Biol. Med. 226: 498, 2001) or Olsen et al. (Lancet 339: 1003, 1992) for reasons of record in the prior rejection of the similar subject matter of these claims.

Applicant's arguments filed 18 August 2006 have been fully considered but they are not deemed to be persuasive.

Notwithstanding applicant's suggestion to the contrary, Leavitt et al. teach their determinations of biochemical markers of impending imminent preterm delivery and of fetal membrane status to aid clinical decisions regarding administration of treatments to prolong pregnancy in pregnant patients at 12 to 37 weeks gestation (see e.g. pages 4-6, 8)

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). For example, applicant urges that Leavitt et al. do not teach determination of estriol. This is not found persuasive for the reasons of record because certain of the rejected claims do not require estriol determination because it is recited in the alternative. Moreover, for reasons of record, the inclusive list of biochemical markers of impending imminent preterm delivery in Leavitt et al. does not exclude estriol and its inclusion or substitution as such would have been obvious in view of Dullien. Applicant urges that Johnson et al., Meis et al., Keirse, or Allen et al. do not teach determinations of markers in their patients selected by other criteria as being at high risk for preterm delivery. This is not found persuasive for the reasons of record in view of the teachings in Leavitt et al. to test such patients in their method. Applicant urges that Leavitt et al. do not teach the specific use of progestational agents as the agents to prolong the pregnancy determined to be at risk for preterm delivery in the absence of ruptured membranes. This is not found persuasive for the reasons of record in view of the direct suggestion in the reference of Leavitt et al. to treat patients identified as such and in view of, firstly, the teachings of Johnson et al., Meis et al., Keirse, or Andersen et al., or, secondly, the teachings of Allen et al. or Olsen et al. Applicant urges that Dullien does not

teach the specific use of progestational agents. This is not found persuasive for the reasons of record in view of the direct suggestion in the reference of Leavitt et al. to treat patients identified as at risk for preterm delivery in the absence of ruptured membranes and in view of, firstly, the teachings of Johnson et al., Meis et al., Keirse, or Andersen et al., or, secondly, the teachings of Allen et al. or Olsen et al. In this regard, although not cited in the rejection, the examiner would also point to the treatment of identified patients in Dullien (US 5,370,135).

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR § 1.136(a).

A SHORTENED STATUTORY PERIOD FOR REPLY TO THIS FINAL ACTION IS SET TO EXPIRE **THREE MONTHS** FROM THE MAILING DATE OF THIS ACTION. IN THE EVENT A FIRST REPLY IS FILED WITHIN **TWO MONTHS** OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE **THREE-MONTH** SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR REPLY EXPIRE LATER THAN **SIX MONTHS** FROM THE MAILING DATE OF THIS FINAL ACTION.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James L. Grun, Ph.D., whose telephone number is (571) 272-0821. The examiner can normally be reached on weekdays from 9 a.m. to 5 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le, SPE, can be contacted at (571) 272-0823.

The phone number for official facsimile transmitted communications to TC 1600, Group 1640, is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application, or requests to supply missing elements from Office communications, should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

James L. Grun, Ph.D.
August 30, 2006

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